

REMARKS

I. Status of the Claims

Claims 1-4, 6, 20, 21 and 25 are pending and under active consideration. Claims 7-19 and 26-43 are withdrawn from consideration. Claims 5 and 22-24 are cancelled. Claim 24 is cancelled by way of this amendment. No other claims are amended.

II. Claim Rejections

A. Rejections under 35 U.S.C. §112, first paragraph

Claims 1-4, 6, 20, 21 and 24 are rejected under 35 U.S.C. §112, first paragraph as allegedly lacking full enablement. According to the Office Action, “the specification, while being enabling for: *a pharmaceutical composition comprising an antibody generated using the sFRP-1 of SEQ ID NO: 2...* does not reasonably provide enablement for pharmaceutical compositions comprising antibodies generated using any portions of sFRP-1.” Page 3, lines 2-9.

This rejection is based on a misapprehension of the scope of the claims. The alleged non-enabled portion of the claims pertains to “antibodies generated using *any* portions sFRP-1” (i.e. fragments); however, the claims are directed to antibodies generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen.

Since the Office Action acknowledges that the actual claimed scope (i.e. antibodies generated using the sFRP-1 of SEQ ID NO: 2) is fully enabled (Office Action, page 3, lines 1-7), withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

B. Rejections under 35 U.S.C. §102(e)

I. Claims 20, 21 and 24 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,433,155 (“Umansky”). The Office Action asserts that Umansky discloses a pharmaceutical composition comprising an antibody against a polypeptide of the SARP (secreted

apoptosis related protein) family that includes murine msarp1, as well as human hsarp1, hsarp2, and hsarp3.

According to the Office Action, SARP-2 is also known as sFRP-1 and shares 99.7% similarity to the sFRP protein of SEQ ID NO:2 of the present application and exhibits 100% identity to amino acids 217-231 of SEQ ID NO:2. Since the claims are not directed to antibodies generated by fragments of SEQ ID NO:2, the homology of amino acids 217-231 is irrelevant.

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. *See* MPEP § 2131 (8th Ed., Rev. 4, Jan. 2006). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Office Action concedes that Umansky does not expressly teach pharmaceutical compositions comprising antibodies generated by the full length sFRP protein of SEQ ID NO:2, which is what is presently claimed. Accordingly, each of the elements of the present claims is not present in Umansky. Applicants respectfully request withdrawal of this rejection.

II. Claims 1, 3, 4, 6, 20, 21, 24 and 25 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Rubin et al. (U.S. Patent No. 6,479,255) (“Rubin”). According to the Office Action, “[t]he amino acid sequence of FRP taught by Rubin has 96.5% local similarity to SEQ ID NO: 2 of the instant application.” Applicants respectfully traverse this rejection based on the following.

The Office Action concedes that Rubin does not expressly teach pharmaceutical compositions comprising antibodies generated by the sFRP protein of SEQ ID NO:2, as presently claimed. Accordingly, rejection of the present claims as being anticipated by Rubin is improper. Applicants respectfully request withdrawal of this rejection.

III. Claims 1, 3-4, 6, 20, 21, 24 and 25 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Rubin *et al.* (US 2003/0175864 A1, with a provisional filing date of May 29, 1997) (“Rubin II”). Applicants respectfully traverse this rejection based on the following.

Citing paragraph [0090] in Rubin II, the Office Action asserts that Rubin II teaches an FRP amino acid sequence having 100% similarity to SEQ ID NO:2 of the instant application. *See* page 9, lines 6-8. There are no sequences listed in paragraph [0090] of Rubin II. Accordingly, it is unclear where a sequence having 100% similarity to SEQ ID NO:2 is disclosed.

Since the Office Action fails to properly support the allegation that a prior art sequence having 100% similarity to SEQ ID NO:2 is used as an immunogen for the generation of antibodies, as presently claimed, a *prima facie* case of anticipation has not been established. Withdrawal or clarification of the rejection is respectfully requested.

C. Rejections under 35 U.S.C. §103(a)

Claim 2 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Rubin *et al.* (U. S. Publication 2003/0175864) (“Rubin II”) in view of Chan *et al.* (*J. Biol. Chem.*, 1992, 267(35):25202-25207) (“Chan”).

The Office Action cites Rubin II for its teachings relating anti-FRP antibody compositions (including agonist, antagonist, and neutralizing antibodies) and pharmaceutical uses of these compositions. The Office Action asserts that “Rubin *et al.* reference teaches all limitations recited in the claims, including the amino acid sequence of sFRP-1 of SEQ ID NO:2, except that the FRP protein is from human osteoblast cells (claim 2).” Page 10, last paragraph. Applicants respectfully traverse this rejection based on the following.

As discussed above, the Office Action has failed to identify, in Rubin II, a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2.

For a claim to be obvious under U.S. patent law, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Additionally, the Patent Office must articulate the reason(s) why a skilled

artisan “would have recognized” that the results of the prior art “were predictable” (*see* Examination Guidelines, Department of Commerce, *Federal Register*, 72(195):57529 (October 10, 2007). Nothing in Rubin II’s general teaching regarding an anti-RFP antibody and Chan’s description of rat Fz-1 and Fz-2 proteins would lead one of ordinary skill in the art to the claimed pharmaceutical compositions comprising antibodies generated using secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2.

Therefore, reconsideration of claim 2 and withdrawal of the rejection of this claim under 35 U.S.C. § 103(a) is requested.

CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed. If there are any issues remaining, which the Examiner believes could be resolved through an interview, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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